	Application No.	Applicant(s)
Notice of Allowability	10/076,213	CHAN ET AL.
	Examiner	Art Unit	
	Jennifer I. Harle	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *08/08/05*.

2. ☒ The allowed claim(s) is/are *17-33*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All   b)☐ Some*   c)☐ None of the:

        1. ☐ Certified copies of the priority documents have been received.

        2. ☐ Certified copies of the priority documents have been received in Application No. _____ .

        3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

    * Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.

    (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached

        1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____ .

    (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of

    Paper No./Mail Date _____ .

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)

2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)

3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____

4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material

5. ☐ Notice of Informal Patent Application (PTO-152)

6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *09132005* .

7. ☒ Examiner's Amendment/Comment

8. ☐ Examiner's Statement of Reasons for Allowance

9. ☐ Other _____ .

DETAILED ACTION

1.   Claims 17-33 are pending.

EXAMINER'S AMENDMENT

2.   An examiner's amendment to the record appears below. Should the changes and/or

additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR

1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the

payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with

David W. Evans on September 7, 2005. The application has been amended as follows:

17. (Currently Amended) A process for minimizing thermal aggregation of DNase in a liquid

solution comprising:

a) introducing a DNase aggregation-inhibiting amount of a sugar <u>that is a disaccharide</u> to

a solution comprising a human DNase, and

b) elevating the temperature of said DNase solution to above 37°C,

wherein aggregation of said DNase at said elevated temperature is reduced as compared

to <u>said</u> DNase in said liquid solution without said DNase aggregation-inhibiting amount of <u>the</u>

<s>said</s> sugar.

24. (Currently Amended) A process according to claim 17, wherein said sugar is selected from

the group consisting of α-lactose monohydrate, ~~mannitol,~~ trehalose and sucrose.

26. (Currently Amended) A DNase solution comprising a human DNase and a DNase

aggregation-inhibiting amount of <u>a</u> sugar <u>that is a disaccharide</u> wherein said DNase solution is

minimally aggregated when said solution is at a temperature greater than 37°C.

32. (Currently Amended) A DNase solution according to claim 26, wherein said sugar is

selected from the group consisting of α-lactose monohydrate, ~~mannitol~~, trehalose and sucrose.

33. (Currently Amended) A composition comprising a therapeutically effective spray-dried,

respirable DNase-containing powder made from the DNase solution according to claim 26.

3.   Support for the amendments to the claims can be found for example on page 18.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Jennifer I. Harle whose telephone number is (571) 272-2763.

The examiner can normally be reached on Monday through Thursday, 6:30 am to 5:00 pm,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

                                        Jennifer I. Harle
                                        Examiner
                                        Art Unit 1654

September 13, 2005

                                        CHRISTOPHER R. TATE
                                        PRIMARY EXAMINER